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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/005,666      | 11/02/2001  | J. Gut               | DT-6018             | 7569             |

7590 09/22/2003

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| EXAMINER |
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LY, CHEYNE D

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/005,666             | GUT ET AL.          |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Cheyne D Ly            | 1631                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 &amp; 3</u> . | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

1. Claims 1-6 are examined on the merits.

**PRIORITY**

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Switzerland on November 03, 2000. It is noted, however, that applicant has not filed a certified copy of the (EP) 00811026.4 application as required by 35 U.S.C. 119(b).

**OBJECTIONS**

3. The abstract of the disclosure is objected to because it exceeds 150 words. Correction is required. It is suggested that Applicant submit the amended abstract on its own separate sheet of paper. See MPEP § 608.01(b).

**CLAIM REJECTIONS - 35 USC § 101**

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.
6. Claims 1-4 are rejected due to the claimed subject matter being directed to a system comprising a database wherein the descriptive material within the database is considered to be either functional, a system and computer readable media; or non-functional, drug data, which are regarded as non-statutory subject matter. The MPEP indicates that descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106 (IV)(B)(1) (b)). Specific to the instant case, database merely stores drug data so as to be

read without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer (MPEP § 2106 (IV)(B)(2) (a)).

7. Claims 5-6 are rejected due to the claimed subject matter being directed to a non-statutory subject matter due to lacking any physical steps such as displaying the stored information from the database. Currently, the steps are merely algorithmic processes of manipulating data directed to drug information without providing a means of visualizing the results of the said processes; therefore, the claim subject matter lacks a real world value. The claimed invention as a whole is directed to a combination of interrelated elements, which combine to form a machine for storing drug data in a database without providing a means for displaying the stored drug data. The critical steps of displaying the drug information would cause the subject matter in its entirety to be a practical application (MPEP § 2106 (IV)(B)(2) (b)).

**CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH**

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Regarding claim 1, lines 10, 22, 27, and 31-32; claim 2, line 5; and claim 3, line 2, the phrase "for example" or "i.e." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

11. Regarding claim 1, lines 25 and 31, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

12. Specific to claim 1, the preamble recites a system for registration, identifying and processing while the body of the claim does not recite any limitations, which provide the means for registration or identifying. The claim is vague and indefinite because it is clear how the process of registration or identifying is achieved there is not any means for achieving either. There is not any clarity as to whether the preamble or the body of the claim is controlling the metes and bounds of the claim. Clarification of the metes and bounds is required. Claims 2-6 are rejected for being dependent from claim 1.

13. Specific to claim 5, lines 1 and 4, the term "carry/ing out" causes the claim to be vague and indefinite because it is unclear what is being carried out (the system of claim 1 or the steps of the method). Clarification of the metes and bounds is required.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ogata et al. (January 1999).

16. Ogata et al. discloses KEGG, a system for linking individual genes to biochemical pathways (page 29, column 2, lines 36-41). KEGG is tightly integrated to the LIGAND

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chemical database (page 29, column 2, lines 1-7). KEGG provides tools for predicting and correlating gene expression data generated from microarray (gene chip) (Abstract etc., page 30, column 1, lines 8-11, Figure 2, and Table 3). KEGG is available via the Internet (Abstract etc.), as in instant claims 4 and 6.

17. As cited by Ogata et al. reference 2, Goto et al. discloses a system for linking chemical, molecular modeling, and GenBank data (page 591, column 1, lines 35-37 to column 2, lines 1-8). The Merck Index is consulted for biochemistry and organic chemistry data (page 593, column 2, lines 31-33).

18. A document from GenBank (NM\_000446) is provided not as prior but only to disclose that GenBank as cited above is a database that has data from different studies directed to gene expression (page 9, Reference 37); genetic polymorphism (page 9, Reference 36); genetic and allelic variations as directed to patients and CAD risk (page 9, Reference 35); and aging (page 9, Reference 34), as in instant claims 2, 3, and 5.

19. A document from Merck Co., Inc. is provided not as prior but only to disclose that the type data available from the Merck Index via LIGAND as cited above. The Merck Index discloses drug data as directed a variety of drug and pharmaceuticals in the area of chemical formula and structure, therapeutic category, clinical trials (safety and efficacy of drugs) and toxicity studies (pages ix-x), as in instant claim 1.

#### **CONCLUSION**

20. NO CLAIM IS ALLOWED.

21. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

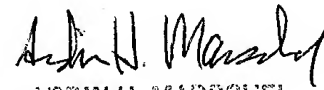
in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

24. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
9/15/03

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER